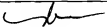



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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 101.1676101	
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on <u>OCTOBER 16, 2007</u>		First Named Inventor <b>DAVID J. PARINS</b>	
Signature 		Art Unit 3736	Examiner RENE T. TOWA
Typed or printed name <u>THU H. LE-TO</u>			
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. <input checked="" type="checkbox"/>			
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The review is requested for the reason(s) stated on the attached sheet(s). <input checked="" type="checkbox"/> Note: No more than five (5) pages may be provided.			
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<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>41,376</u>		612.677.9050 Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		<u>October 16, 2007</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	DAVID J. PARINS et al.	Confirmation No.:	1930
Serial No.:	10/748,933	Examiner:	RENE T. TOWA
Filed:	DECEMBER 30, 2003	Group Art Unit:	3736
Docket No.:	1001.1676101	Customer No.:	28075
Title:	DISTAL ASSEMBLY FOR A MEDICAL DEVICE		

**PRE-APPEAL CONFERENCE BRIEF**

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Date

Appellants have carefully reviewed the Final Office Action of May 29, 2007 and the Advisory Action of August 16, 2007. Currently, claims 1, 3-15, 17-54 and 59-62 are pending and have been rejected and claims 23-54, 61 and 62 have been withdrawn from consideration. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson et al., U.S. Patent No. 6,673,025 (hereinafter "Richardson"). However, Richardson does not disclose all the elements of the claims.

In the Advisory Action, the Examiner argues, based on statements in the specification in the *present application* about a tubular member, that, in Figure 23 of Richardson, one should consider polymer layer 191 to not extend distally of solder mass 185. There are several errors here. First, the construal of "tubular member", purportedly based on the specification, is based on phrases only found in the claims. Second, the term "tubular member" has been construed incorrectly. Third, the evaluation what Richardson discloses in light of what "tubular member" means is, for lack of a better term, backwards.

The phrases relied on in construing “tubular member”, “is disposed about and connected to the distal end of the core member” and “connected to the coil member” are not in the specification. In the application as filed, the first phrase is found only in claim 1 and the second phrase is not found at all. As quoted in the Advisory Action, “when a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must *clearly express* that intent in the written description.” (Italics added.) Phrases not found in the written description can hardly be clear expressions of intent to redefine a term.

Second, even though these phrases accurately reflect the spatial relationship between the tubular member and the core and coil members in at least one claimed embodiment, they still are not phrases which would redefine “tubular member.” In *Phillips v. AWH Corp.* (cited in the Advisory Action), the court construed the term “baffles.” The court writes, “Dependent claim 2 states that the baffles may be ‘oriented with the panel sections disposed at angles for deflecting projectiles such as bullets able to penetrate the steel plates.’ The inclusion of such a specific limitation on the term ‘baffles’ in claim 2 makes it likely that the patentee did not contemplate that the term ‘baffles’ already contained that limitation.” *Phillips v. AWH Corp.* 75 USPQ2d 1321, 1324 (Fed. Cir. 2005). In like manner, the use of the phrases “disposed about and connected to the distal end of the core member” and “a coil member connected to the tubular member” in pending claim 1 makes it apparent to the reasonable reader that appellants did not contemplate that the term “tubular member” included such limitations.<sup>1</sup>

Finally, the Examiner errs in arguing that the tip of the guidewire of Figure 23 of Richardson is not part of the tubular member. The Examiner makes this argument in order to be able to say that Richardson meets the elements of the claims, such “the distal end of the coil member extends distally beyond the distal end of the tubular member” in claim 1. However, the tip of the guidewire in Richardson, which is to say the part of the guidewire distal of solder mass 185, is part of polymer layer 191 – the element of Richardson that the Examiner says corresponds to the tubular member of the claim. The ordinary meaning of member is “a distinct part of a whole” and nothing in the specification or drawings suggests that the term “tubular member” as used in this application can be an arbitrary portion of some larger component. To

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<sup>1</sup> The specification does describe the tubular member, making it clear that the term encompasses more than a simple tube. See, for example, the two paragraphs beginning at page 5, line 6. However, the specification does not define “tubular member” relative to other components. (Whether a guidewire having a tubular member is covered by the claim language does, of course, depend on the relative spatial relations of the guidewire components.)

the contrary, “tubular member” is used throughout the specification in a manner consistent with this ordinary definition of the term. For example and as discussed above, the term is not limited by any spatial relationship with another guidewire component. Likewise, appellants’ consistent use of the term “portion” in the specification and the claims (see claim 6, for example) makes it clear that applicants understand the difference between a “member” and some smaller constituent thereof such as a “portion”. Therefore, a reasonable person of skill in the art would not read the application and understand terms like “core member”, “tubular member” or “coil member” to apply to arbitrary and indistinct portions of components of a guidewire. A reasonable person of skill in the art reading the application to compare it with Richardson would therefore understand that polymer layer 156 of Figure 20 or polymer layer 191 of Figure 23 would have to be considered as a whole, because only the whole is a member, and would not correspond to the tubular member of, for example, claim 1 because these layers extend distally beyond the distal end of the coil member. Only by twisting the meaning of the claim terms beyond the broadest reasonable interpretation can one find that the pending claims are obvious over Richardson.

Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Hodgson, U.S. Patent No. 5,345,945. Hodgson is apparently used by the Examiner as disclosing a guidewire where a coil extends distally beyond the distal end of a tubular member. The Examiner argues that it would have been obvious to modify the Figure 20 embodiment of Richardson in view of Hodgson (1) “since such a modification would serve the same purpose of enhancing the performance of the guide and providing a guidewire with a substantially constant outer transverse dimension which translates smoothly in an axial direction” and (2) “since such a modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire.” The two problems with these supposed motivations are that Richardson already teaches these things and that making the proposed modification would not necessarily result in the claimed invention. The embodiment of Figure 20 of Richardson, the embodiment that the Examiner bases this rejection on, shows a guidewire with a substantially constant outer transverse dimension. Adding the coil of Hodgson would not make the outer transverse dimension more constant. Likewise, Richardson teaches that one can make the polymer layers and the helical coil of embodiment 20 radiopaque. Richardson teaches in column 20, lines 53-58 that “excepting noted differences, the features...of guidewire 140 can be generally the same as the features...of similar elements of

guidewire 110 discussed above.” Guidewire 140 is the guidewire of Figure 20 and guidewire 110 is the guidewire discussed immediately before guidewire 140. Richardson teaches two different methods of making guidewire 110 radiopaque. First, “other materials suitable for the proximal helical coil...and suitable for the helical coils of other embodiments of the invention discussed herein, can include radiopaque metals and alloys.” Column 18, lines 10-14. Second, in reference to a polymer layer to dispose about the core member and coils, “any of the aforementioned polymers may be loaded with additives to control the physical properties such as flexural modulus, hardness and radiopacity.” Column 19, lines 45-47. The disclosure with respect to Figure 20, therefore, already discloses a fluoscopically trackable guidewire in which the whole of the distal end, if desired, is radiopaque and adding a coil from Hodgson would not enhance this radiopacity.

Further, the radiopacity of the coil of Hodgson and its position in the guidewire are not related to where it is with respect to a tubular member and therefore adding the coil of Hodgson to the guidewire of Richardson would not necessarily (or is even likely to) result in the claimed invention. The coil of Hodgson extends distally of the tubular member of Hodgson in part because the tubular member of Hodgson terminates well before the distal end of the guidewire. This is not the case with the tubular member of Richardson, which except for an outer polymer layer, extends distally to the distal tip of the guidewire. Therefore, even if one were to modify Richardson by adding the coil of Hodgson, the result would not necessarily or likely be a guidewire where a coil extends distally of a tubular member. The coil of Hodgson, for example, can be wound around the tubular member and provide to Richardson the benefits of the two motivations given by the Examiner. Because there is no motivation to combine Richardson in view of Hodgson and because this combination would not result in the claimed invention, appellants submit that this rejection is clear error.

Claims 8, 11, 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Palmer et al., U.S. Patent No. 6,544,231 (hereinafter “Palmer”) and over Richardson in view of Hodgson and Palmer. Palmer is cited by the Examiner as disclosing “a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding” and the Examiner therefore considers that it would be obvious to make the proposed modification “in order to tightly fuse metal elements together.” The problem with this rejection is that the tubular element of Richardson cited as anticipating the tubular member of claim 1 is

polymeric. See, for example, Richardson at column 20, lines 8-9. One would not laser-weld the metal coil of Richardson to the polymeric sleeve because the materials are not laser weld compatible. A prima facie case of obviousness has not been made, therefore, at least for the reasons that no motivation to combine the references exists and there is no reasonable chance of success of doing so.

Claims 9-10 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Palmer further in view of Cook et al., U.S. Patent No. 5,213,111 (hereinafter "Cook") and over Richardson in view of Hodgson, Palmer and Cook. Cook is cited as disclosing "a guidewire wherein a coil member 151 is connected to a core member through crimping." However, these claims pertain to the connection of the tubular member to the core; for example, claims 10 recites "wherein the tubular member is connected to the core member through crimping." The proposed modification, therefore, would not result in the claimed invention. Further, the tubular member of Richardson is polymeric, which so far as applicants know, is not a material compatible with a crimping process. Further, Richardson teaches away from crimping the coil; Richardson teaches a manufacturing process that "can relieve stresses that can build up during construction of the guidewire 140 and provide for improved handling characteristics." Richardson at column 20, lines 36-39. As crimping the coil would introduce stresses, this process would produce an inferior guidewire while providing no other benefit applicants can discern.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
DAVID J. PARINS et al.

By their attorney,

Date: October 16, 2007



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